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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,728	01/29/2004	Moises Calderon		7953

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HOLLAND & BONZAGNI, P.C.
171 DWIGHT ROAD, SUITE 302
LONGMEADOW, MA 01106-1700

EXAMINER	
HOLMES, REX R	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,728	CALDERON, MOISES	
	Examiner	Art Unit	
	Rex Holmes	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *13-17 and 20* is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/07 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. (Patent No. 4,662,355) in view of Leschinsky et al. (Patent No. 5,439,448).

Pieronne et al. disclose a system and method for pump-assisted myocardial revascularization without cardiopulmonary bypass comprising: surgically attaching a first cannula to the aorta (Fig. 1, element 14; Col. 2, lines 60-62); surgically attaching a second cannula the left atrium (Fig. 1, elements 1; Col. 2, lines 41-43); interconnecting the first and second cannulae with a first atrial-arterial shunt comprising a section of tubing having first and second ends and an interior (Fig. 1, element 3; Col. 2, lines 44-46); priming the shunt to remove air (Fig. 1, elements 4, 6, and 13; Col. 2, lines 47-48 &

66; Col. 3, lines 12-17); inserting the shunt tubing into a first peristaltic pump (Fig. 1, elements 7 & 8); and activating the pump to pump blood through the shunt and in parallel with the patient's heart pumping action (Col. 1, lines 6-11; Col. 7, lines 52-58). Regarding first and second cannula adapters, each with a vent for priming, see the Pieronne et al. Fig. 1 on the Office Action mailed 4/24/06 where examiner marked the structure considered to meet these claim requirements. Here, examiner considers that the Pieronne et al. "air purges" (i.e. vents for priming purposes) inherently include a sealing means for selectively opening and closing the vents. Without such sealing means, the vents would create deleterious open holes in the blood circuit.

2. Pieronne et al. do not explicitly disclose that the section of tubing is translucent. Leschinsky et al. disclose a method and apparatus for interconnecting blood-carrying tubing, cannulae, and/or external pumps and provide a teaching that blood-carrying tubing is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Leschinsky et al. to modify the tubing of Pieronne et al. to be translucent. The motivation would have been to enable the clinician to view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9).

3. In addition, Pieronne et al. do not explicitly disclose a cap removably attached to each vent. The system and method of Leschinsky et al. further includes vents for removing air from the a blood-carrying circuit, wherein the vents include removably attached caps for selectively opening and closing the vents during priming (Fig. 5, elements 28 & 32; Figs. 8, 9, & 10, elements 128 & 132; Col. 7, lines 39-55; Col. 9, lines

16-57). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Leschinsky et al. to modify the priming vents of Pieronne et al. to include removably attached caps. The motivation would have been to provide an easy, well-known means for closing the vents during normal pumping and for opening them during priming to allow air bubbles to escape to the external environment.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and further in view of Aboul-Hosn et al. (Patent No. 6,935.344).

5. As related above with respect to claim 1, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Pieronne et al. do not explicitly disclose that the pump is placed within one meter of the patient or that the tubing is no longer than two meters. Aboul-Hosn et al. disclose systems and methods for left and right side heart assistance including the use of shunt tubing and peristaltic pumps (Fig. 5; Col. 18, lines 41-54). Additionally, Aboul-Hosn et al. teach that it is important to bring the pump as close to the patient as possible and to minimize priming volume, the volume of the support system that is external to the patient (Col. 5, lines 2-16; Col. 17, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Aboul-Hosn et al. to modify the heart support system of Pieronne et al. to include placement of the pump within one meter of the patient and to utilize tubing that is no longer than two meters. The motivation would have been to provide well-known advantages of

minimizing the distance and time that blood travels outside the body, such as preventing the occurrence of hemolysis and eliminating the necessity of cooling or warming the blood (Col. 17, lines 24-39).

6. Claims 4, 6, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al. and further in view of Rawles et al. (Patent No. 6,890,316).

7. As related above, Pieronne et al. disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Comments made above in rejection of Claims 1 and 2 apply here as well. However, Pieronne et al. do not explicitly disclose that the above-described atrial-arterial shunts are packaged in a sealed, openable container having a sterile interior. Rawles et al. disclose a tubing set for a blood handling system that includes placing the tubing in a sealed, openable container having a sterile interior (Fig. 5, elements 60 & 65). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Rawles et al. to modify the heart support system of Pieronne et al. to include such sterilized packaging of the shunt prior to its use in the pumping system. The motivation would have been to prevent contamination of the tubing, and possible subsequent contamination of the patient's blood, while handling it before connection to the cannulae.

8. With respect to the limitation of claim 4 that the vent "further comprises two clamps removably attached to the cannulae to block a patient's blood flow until priming as desired," Pieronne et al. fails to explicitly disclose that the left side assistance system

may include such clamps. However, it is well known in the art to utilize clamps for controlling fluid flow in extracorporeal tubing systems (for example, see Leschinsky et al. in the background section describing that extracorporeal tubes are each clamped to control fluid flow in a prior art priming procedure; col. 1, lines 40-45. Examiner notes that class 604/250 contains 400 patents or publications relating to such clamps for pinching conduits or tubes to control flow of material to or from the body). More particularly, Rawles et al. teaches that all of the valves of the extracorporeal tubing set used in the priming circuit preferably comprise well-known pinch clamps that engage an exterior surface of the tubing (see col. 6, lines 23-39; see also col. 9, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the sterilized packaging of Pieronne to include pinch clamps as taught by Rawles in order to supply medical personnel with all equipment necessary or desired for the priming procedure.

9. Claims 7, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. in view of Leschinsky et al., and further in view of Rawles et al. as applied to Claims 4, 6, 8, 9, and 11 above, and further in view of Aboul-Hosn et al.

Comments made above in rejection of Claim 3 regarding tubing length that is no longer than two meters apply here as well.

Allowable Subject Matter

10. Claims 13-17 and 20 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The subject matter of independent claims 13 and 20 could not be found or was

not suggested in the prior art. The subject matter not found was the priming of the shunt with blood flow from the patient to remove air from the shunt, in combination with the other steps in the claim.

Response to Arguments

11. Applicant's arguments filed 3/5/07 have been fully considered but they are not persuasive.

12. Applicant first argues that Pieronne does not teach or suggest that the air purging can be done by patient's own blood, as required by amended claims 1 and 4. However, the claim recitation "for priming the vent with blood flow from the patient" as recited in claim 1 is merely a statement of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the intended use recitation does not result in a structural difference between the claimed invention and Pieronne, such a recitation is not given patentable weight.

13. Lastly, Applicant argues that there is no teaching in any of the cited patents to combine them in the manners proposed in the Office Action mailed 4/24/06, and that the examiner's conclusion of obviousness is based upon improper hindsight reasoning.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references are found in the references themselves and are in the knowledge generally available to one of ordinary skill in the art as described in the rejections above. For example, with respect to claim 1, the motivation to modify the tubing of Pieronne et al. to be translucent is found within the teaching reference, Leschinsky et al. (the motivation would have been to enable the clinician to view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9)).

14. In response to the argument of improper hindsight, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

15. Applicant's amendments filed 3/5/07, with respect to claims 4 and 6-12 have been fully considered and overcome the 35 USC 112 2nd objections. The 35 USC 112 objections of claims 4 and 6-12 have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rex Holmes
Examiner
Art Unit 3762

George Evanisko
Primary Examiner
Art Unit 3762

5/17/7